ACTIVE study for small cartilage defects of the knee: Safety of CartRevive hydrogel in 10 patients at 3 months post-surgery

A multi-center, pivotal, prospective trial

G.S. v.d. Weiden[1-3], N v. Egmond[2], B.M. Kalkman[2], M. Karperien[3], S.K. Both[3], S.C. Mastbergen[1], P.J. Emans[4], J.J. Caron[5], R.J.H. Custers[2]

1 Rheumatology & Clinical Immunology, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands.
2 Department of Orthopedic Surgery, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands.
3 Developmental BioEngineering, University of Twente, Enschede, The Netherlands
4 Department of Orthopedic Surgery, Joint-Preserving Clinic, Maastricht University Medical Center, Maastricht, The Netherlands.
5 Department of Orthopedic Surgery, Elisabeth-TweeSteden Hospital, Tilburg, The Netherlands.

UMC Utrecht The Netherlands | Hy2Care | UNIVERSITY OF TWENTE.

Introduction

Cartilage defects of the knee have poor intrinsic healing capacity and can lead to functional disability and osteoarthritis

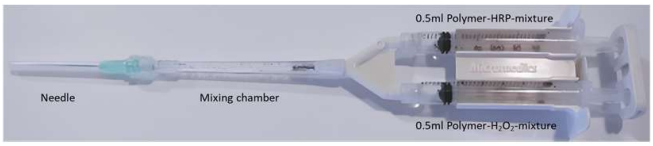
ACTIVE (Advanced Cartilage Treatment with Injectable-hydrogel Validation of the Effect)

- The CartRevive® Hydrogel implant is a novel treatment for cartilage defects in the knee.
- Composed of a mixture of natural polymer conjugates that are mixed intra-operatively and which cross-link in situ through a mild enzymatic reaction, providing a cell-free scaffold for cartilage repair

Purpose

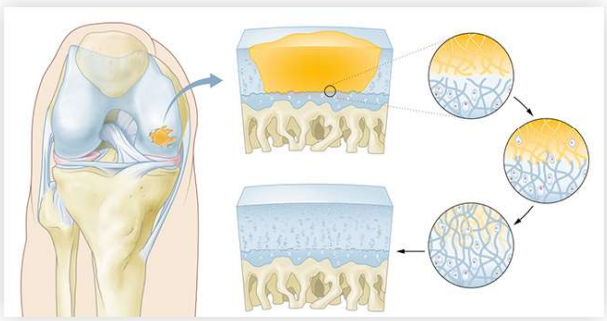
To demonstrate safety of this innovative cartilage repair procedure for small (0.5-2.0cm2) articular cartilage defects in the knee.

Methods



10 patients with cartilage defect on the femoral condyle or trochlear groove treated with CartRevive hydrogel.

- ICRS grad IIIA/IIIB
- Numeric Pain Score (NRS) ≥ 4
- Defect size (0.5-2.0cm2)



All patients had >3 months of follow-up

- Physical examination (baseline, 1 day, 1 week, 1 and 3 months postoperatively)
- Inflammatory markers until normalized
  - C-reactive protein
  - Erythrocyte-sedimentation-rate
  - Leukocytes

All clinical data and (serious) adverse events were recorded.

Baseline	N=10
Age (years), mean (SD)	30.5 (9.2)
Male gender, *n* (%)	7 (70%)
BMI (kg/m^2), mean (SD)	25.3 (1.8)
Defect size (cm), mean (SD)	1.2 (0.4)

Results

No adverse foreign tissue reactions were observed

No serious adverse events were recorded

No significant changes in vital signs

Inflammatory markers normalized in all patients at 1 week to 1 month after surgery.

Mean flexion ± SD of the index knee was 128.5 ± 12.5 degrees after 3 months.

NRS (average pain score over last 7 days) at 3 months was 2.2 ± 2.0.

Conclusion

This first in man study showed safety for the CartRevive® Hydrogel implant, in patients with small articular cartilage defects in the knee at the 3-month safety endpoint.

These results provide a solid basis for continuation and expansion of this unique cartilage treatment.

Contact: G.S.vanderweiden@umcutrecht.nl